

shown herein below and a marked-up version entitled "Marked-Up Version of Amended Claims" is attached hereto as a separate page.

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1. (AMENDED) A balancing disc for an orthotic foot device comprising:

C' a substantially circular member having a planar top surface and a planar bottom surface, the surfaces being inclined at an angle with respect to each other, the disc being securable to the orthotic foot device in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution.

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#### **REMARKS**

By this Reply, Claim 1 is amended. Accordingly, upon entry of this Reply, Claims 1, 7 and 8 are pending and reconsideration is requested.

Further, FIGS. 1 and 3 of the drawings were amended. No new matter is introduced.

Submitted herewith for inclusion in this Application is a copy of Applicant's "Affidavit Under 37 CFR 1.132." This Affidavit was entered in the parent application (now USP 6,098,319).

#### **The Examiner's Action**

The Examiner rejected Claims 1 and 7 – 8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 2 of United States Patent No. 6,098,319, and rejected all of the

claims under 35 USC Section 103(a) as being obvious in view of a combination of prior art patents.

To advance prosecution on the merits, submitted herewith is Applicant's "Terminal Disclaimer" [PTO/SB/26 (10-00)] and associated fee (37 CFR 1.20(d)). Accordingly, Applicant's Attorney submits that the Examiner's double-patenting rejection is obviated.

**Rejection of Claims Under 35 USC Section 103 (a): Obviousness:**

The Examiner rejected Claims 1 and 7 – 8 under 35 USC 103 (a) as being "unpatentable over Kantro (5,170,572) in view of Cherniak (3,099,267) alone, or further in view of Shaw (1,958,097), Smith (5,345,701) and Marc (5,068,983)", for reasons given.

Applicant's Attorney traverses the Examiner's rejection(s) under 35 USC Section 103.

Prior to discussing the obviousness rejection, the invention will be discussed briefly.

**Applicant's Invention:**

Applicant's invention is directed to an orthotic balancing disc for providing balance and weight distribution adjustment, which is easily integrated with existing orthotic foot devices as well as into other footwear items or devices. Desirably, these discs are available to the practitioner in "kit" form to select a specifically configured disc to effect a proper fitment.

Heretofore, in attempting to effect proper balance and weight distribution, a skilled foot technician would have to initiate a time consuming task of making

minute corrections to the orthotic foot device by emplacement of wedges in correct orientation. In accordance with the invention herein, there is provided a wedge shaped circular disc which is particularly adapted to be securable to an orthotic device in a plurality of incremental orientations through 360° to provide the requisite adjustment for effecting proper balance and weight distribution.

According to the invention, Claim 1 is directed to a balancing disc that comprises a substantially circular member having planar upper and lower surfaces, the upper and lower surfaces being angularly inclined with respect to each other by an angle, the disc being securable to an orthotic foot device in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution.

Further, Claim 7 is directed to a balancing disc for balancing the gait of a user and requires that the disc be substantially rigid, wedge shaped, the surfaces be planar, and the required angle of inclination be about 2° to 6°, the disc being attachable to a footwear item for imparting proper weight distribution and balance to the user.

Claim 8, dependent upon Claim 7, further requires that the disc be formed of a substantially non-compressible solid material selected from the group consisting of leather, rubber or plastic.

Applicant's Attorney submits that Claims 1 and 7 – 8 patentably define over the prior art and are not rendered obvious by the art relied on by the Examiner.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. ACS Hosp. System, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577; 221 USPQ 929, 933 (Fed. Cir. 1984).

As understood, the Examiner's Section 103(a) rejection is a multipart rejection: (a) Kantro in view of Cherniak, alone; or (b) Kantro in view of Cherniak and Shaw; or (c) Kantro in view of Cherniak and Smith; and/or (d) Kantro in view of Cherniak and Marc.

That is, the Examiner's rejection under 35 USC Section 103 is not believed to comprise a reconstruction that combines in one rejection features taken from all of the prior art cited (viz., Kantro in view of Cherniak, and Shaw, and Smith, and Marc). If so, Applicant's Attorney submits that there is no suggestion in the collage of references, taken alone or in combination, for such a reconstruction. This combination would be pure ~~a pure~~ hindsight reconstruction, picking and choosing whatever parts are needed from each reference while rejecting that which would teach against such reconstruction.

Applicant's Attorney submits that the prior art relied upon by the Examiner does not render Applicant's claims obvious. Key differences between the cited reference(s) and Applicant's invention, as claimed herein, is that the prior art (a) teaches away from the invention herein by teaching the use of compressible

cushions, (b) does not teach or suggest that the disc have a specific angle of inclination; and/or (c) does not teach or suggest that the disc be securable to the orthotic foot device in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution.

Kantro, Shaw, Smith and Marc are directed to cushions. A cushion can never impart balance. Applicant's claimed invention is not a cushion but rather a rigid circular orthotic device providing a biomechanical control for balance.

As stated in Applicant's Affidavit Under 37 CFR 1.132, as understood by those skilled in the art of orthotics, there is a difference between balancing a gait and cushioning. The word "cushion" implies a collapse of the structure or a flexure of the body of the device. A cushion is used to accommodate, rather than provide biomechanical control.

The Examiner's rejection of Claims 1, 7 and 8 based on Kantro in view of Cherniak is believed to be a hindsight reconstruction.

Kantro teaches that cushions (19, 20 and 21) of a polymeric foam material be placed in specific locations (11, 12 and 13) of a shoe insert (14) to provide tripodal support:

"As weight increases and its distribution on the body changes, more cushioning is required to lessen shock to the foot, also support at the gait points to permit the foot to maintain its proper posture as well as to alleviate stress and strain upward through the legs and into the lower back caused by improper foot posture." (col. 4, lines 35 – 41)

Kantro does not suggest and does not teach the provision of a rigid circular member to provide control in balancing the gait of a user. As noted, a cushion can never impart balance.

In Kantro, the locations (11, 12 and 13) dictate the specific orientation of the cushion geometry, such as regards tapered areas of the cushions (19 and 20). In particular, Kantro teaches:

“To further mitigate the tendency towards pronation, cuboidal cushion 20 is also tapered along (sic) an axis directed at an angle relative to the longitudinal axis of the insole along line 20a toward the gait point located at the base of the first metatarsal bone 9a and the metatarsal cushion 21. This corresponds to the direction of force along line 12a in FIG. (sic) from the calcaneal-cuboid gait point to the first metatarsal base gait point 13.” (col. 4, lines 44 – 52)

“The rotational positioning of cuboidal cushion 20 is such that the taper is angled relative to the longitudinal axis of the insert and the foot toward the base 13 of the first metatarsal bone 9a and metatarsal cushion along line 20a.” (col. 5, lines 37 – 41)

Contrary to that required by Claim 1, Kantro teaches against the provision of a disc that has angled faces and is securable to the orthotic foot device in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution. The disc of Applicant's invention is securable to the insert - either in a desired location on the insert, or also as to the disposition (i.e., direction) of the angled surfaces of the disc relative to an imaginary longitudinal axis passing through the insert.

Cherniak is directed to a foot balancing device comprising, inter alia, a first, second and third set of circular pads (50, 52, and 54), each pad preferably being of uniform thickness, rigid or yieldable, and comprised of rubber, felt, cardboard, pulp products, leather and the like. (See FIG. 9, and col. 2, lines 1 – 2, and col. 4, lines 6 – 9). In Cherniak:

"In all cases, the function of the pads is to lift the weight of the foot off the metatarsal heads so that the weight is balanced on the pads independently of the structural deformation of the skeletal foot and/or imbalance produced by callouses and the like on the bottom of the foot." (col. 4, lines 6 – 9) (Emphasis supplied herein)

Cherniak does not teach and does not suggest a wedge shaped circular disc, which is adapted to be secured in a plurality of incremental orientations through 360° to provide a proper adjustment for effecting proper balance and weight distribution. Indeed, inasmuch as the pads (50, 52, and 54) are flat and circular, Cherniak teaches that to achieve a localized foot lifting function, a continuous array of pads is required and that these pads are placed side-by-side. If the pads (50, 52, and 54) were wedge shaped, it is not clear how Cherniak would orient the angled faces of the individual wedges and also accomplish the foot lifting function. Clearly, Cherniak teaches against any particular benefit being gained from a wedge shaped disc that is oriented relative to an insert onto which secured.

The rejection of Claim 1 is not rendered obvious in view of Kantro in view of Cherniak.

Contrary to Claim 1, Kantro (the primary reference) does not teach a substantially circular member having planar surfaces inclined at an angle relative to one another and securable in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution. To the extent that the Kantro cushion (20) is tapered, Kantro teaches that the cushion is aligned along an axis that is at an angle to the longitudinal axis of the insert. Kantro teaches against incremental orientations of the cushion through 360°. As to the

secondary reference, Cherniak teaches provision of a plurality of flat pads (50, 52, and 54) linearly aligned with one another.

Whether considered alone, or as combined, Kantro and Cherniak do not teach or suggest the requirements of Claim 1. Accordingly, Claim 1, as amended, is submitted as being patentable over the prior art references of Kantro and Cherniak.

Applicant's Attorney traverses the Examiners rejection of Claim 1 based on the combination of Kantro and Cherniak, and further in view of Shaw. The Examiner states that:

"The Shaw '097, Smith '701 and Marc '983 references are cited if for purposes of argument any doubt should subsequently be raised concerning the language in Kantro '572 'tapered along an axis directed at an angle' at column 4, line 46." (Examiners Action, Page 4, lines 2+)

The Examiner relied on the above-noted references as teaching the provision of tapered wedge members: Shaw for inclined wedge members having a tapered portion of about 3°, Marc for a base piece (20) having a tapered portion of 2°, and Smith for correcting wedges (24, 26) tapered at about 4°, concluding that the wedges can be formed at any angle, depending on the patients needs.

Applicant's Attorney traverses the Examiner's multi-part rejections as being based on a hindsight picking and choosing of elements needed from the prior art without a suggestion or motivation in the any of the references for such element.

Kantro fixes the relationship of the cushions' geometry relative to the longitudinal axis of the insert member. The reason for the tripodal placement and cushion orientation was critical and particularly described by Kantro. That is,



Kantro was faced with a specific problem and disclosed a specific solution. The prior art references may show incidental features, but they do not support a finding of obviousness under the factual mandates of 35 USC Section 103.

Shaw and Smith are similar in that each discloses wedge-shaped corrective pads of rectangular configuration, a pad being secured, respectively, to the anterior and posterior portions of an insole and oriented such that each pad (and the tapered faces thereof) extend/face transversely of the longitudinal axis of the insole. There is no suggestion that the wedge shaped corrective pads be circular or orientable through 360°.

Marc discloses a heel shaped element (20) that is inset into a like-shaped receiving cavity (11). The heel (20) of Marc and the cushion (19) of Kantro are similar in that each is wedge-shaped. There is no suggestion that the heel shaped element be circular or orientable through 360°.

Applicant's Attorney submits that Claim 1 is patentable over Kantro, in view of Cherniak, and further in view of Shaw, or Smith, or Marc. Applicant's Attorney submits that Claim 1 is in condition for allowance.

Claim 7 is directed to a balancing disc for balancing the gait of a user. The balancing disc is similar to that required by Claim 1 and further requires that (a) the disc is substantially rigid, and (b) the surfaces of the disc are angularly inclined at an angle of about 2° to about 6°.

As stated herein above, Applicant's balancing disc is required to be a rigid, substantially circular member. The compressible nature of the Kantro

cushion fails to teach or suggest a balancing disc, as required in Applicant's Claim 7.

Further, the Kantro reference does not teach or suggest the provision of a rigid substantially circular wedge member having a 2° to 6° inclination between upper and lower surfaces thereof, as required in Applicant's Claim 7.

With reference to the applicant's affidavit filed under 37 CFR 1.132, the range of two to six degrees is not simply a design choice or routine optimization. This range was specifically chosen as the range covers 90% of all fore foot and rear foot encounters. This allows for use of the device by the great majority of the population without individual customization of the circular wedges.

In analyzing the Kantro reference, the Examiner states:

"Note that heel cushion/disc 19 is tapered at about 5 degrees. It is submitted the only reasonable conclusion (by comparison of column 4, line 32 to line 46) is that cushion 20 is also exactly tapered as described for cushion/disc 19." (Examiners Action, Page 3, line 10+) (Emphasis supplied herein)

Applicant's Attorney **does not find any support** in Kantro for the Examiner's statement that the posterior **cushion (19) is tapered at about 5 degrees**. Even if the cushion (19) has a taper of about five degrees, Applicant's Attorney **strongly disagrees** with the Examiner's contention that "the only reasonable conclusion - - - is that cushion 20 is also exactly tapered". The only reasonable conclusion? Exactly tapered? There is no teaching or suggestion in Kantro for the "one-size angle and shape fits all" contention of the Examiner.

As stated herein above, Cherniak discloses flat a plurality of thin circular pads be arranged in side by side relation. There is no suggestion that these pads (50, 52 and 54) be other than that shown. Cherniak was faced with a different problem, albeit similar, and came up with a different solution than that required by Claim 7.

Contrary to the requirements of Claim 7, Marc and Shaw do not teach or suggest provision of a substantially rigid circular member, or a circular wedge member made of a rigid substantially non-compressible material as required by Applicant's Claim 7.

The combination of Kantro in view of Cherniak, and further in view of Shaw, or Smith, and/or and Marc does not show or suggest Applicant's invention. Indeed, although the prior art references are similar, the combination of teachings would not lead one skilled in the art to Applicant's invention.

Applicant's Attorney submits that Claim 7 is patentable over Kantro, in view of Cherniak, and further in view of Shaw, or Smith, or Marc. Applicant's Attorney submits that Claim 7 is in condition for allowance.

Claim 8 is dependent on Claim 7 and is submitted as being patentable for the same reason that Claim 7 is patentable.

Claim 8 further requires that the disc be formed of a substantially non-compressible solid material selected from the group consisting of leather, rubber or plastic.

The prior art references relied upon by the Examiner are at best inconclusive in what they teach or suggest as to material. For example, Kantro

teaches that the cushions (19, 20, and 21) be comprised of polymeric foam having a density higher than that of the surrounding insole – whether a separate removable insole member (14) or a built in member that is part of the shoe. Smith teaches that the heel piece (20) be constructed of a foam material, preferably a visco-elastic compound, a soft spongy material which absorbs shock.

The Examiner contends that

“ ‘high density foam material’ **must necessarily be sufficiently rigid** to alter the biomechanical balance and weight distribution by providing support at specific points. The structure and function, therefore, are submitted to be the same as applicant’s, notwithstanding the use of the term ‘cushion’.” (Examiner’s Action, Page 3, lines 14+, emphasis in original)

Applicant’s Attorney **strongly disagrees** with the Examiner’s conclusionary assertion that the structure and function of foam material is the same as Applicant’s. Certainly, the conclusion is not supported by the Smith reference. The Examiner is discarding the function of the cushion and supplying teaching not found in Kantro. That is, the Examiner is applying a hindsight reading of Kantro and supplying teaching not found in or suggested by Kantro.

Cherniak suggests that the pads (50, 52 and 54) be comprised of rubber, felt, cardboard, pulp products, and leather. The group of paper, pulp and cardboard products is submitted as modifying the nature of the rubber and leather materials to suggest that Cherniak desires that the material should be “compressible” and not be comprised of a non-compressible material.

Shaw is silent as to the material of the heel member (20).

Smith teaches away from the materials required by Claim 8.

Marc teaches that the sole (30) be comprised of nylon, polystyrene, high density polyethylene and other polymers, but is silent as to the wedges (24 and 26).

Contrary to Claim 8, Applicant's Attorney submits that Kantro (and Smith) does not teach or suggest the provision of a non-compressible material, and that Cherniak suggests that the materials be compressible – not a not-compressible material. The secondary references to Shaw and Marc are believed irrelevant to the issue. Clearly, the prior art does not render Claim 8 obvious under 35 USC Section 103.

Applicant's Attorney submits that Claim 8 is patentable over Kantro, in view of Cherniak, and further in view of Shaw, or Smith, or Marc. Applicant's Attorney submits that Claim 8 is in condition for allowance.

### **Conclusion**

The prior art of record herein, whether considered alone or in combination, does not show or suggest or render obvious under 35 USC Section 103 the orthotic balancing disc as required by Claims 1, 7 and 8.

Applicant's Attorney submits that Claims 1, 7 and 8 define patentably over the prior art, are allowable, and are in condition for allowance.

Accordingly it is respectfully requested that a Notice of Allowance be issued.

If the Examiner believes that a telephone conference would advance the prosecution of this application, he is encouraged to contact this Attorney at the number listed below.

Respectfully submitted,

Date: March 9, 2001



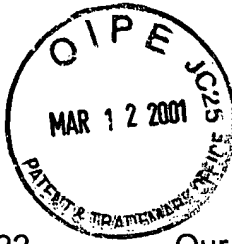
Arnold S. Weintraub

Attorney for Applicant

Registration No. 25,523

(248) 901 - 4043

PLUNKETT & COONEY  
38505 Woodward, Suite 3000  
Bloomfield Hills, MI 48304



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Marked-Up Version of Amended Claims

1. (AMENDED) A balancing disc for an orthotic foot device comprising:  
  
a substantially circular member having a planar top surface and a planar bottom surface, the [sufaces] surfaces being [angularly] inclined [by] at an angle [  $\theta$  ] with respect to each other, the disc being securable to the orthotic foot device in a plurality of incremental orientations through 360° to effect a desired balance and weight distribution.

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